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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,546	10/10/2003	K. M. Slimak	TPP 31413DIV	9719
77176	7590	10/06/2008	EXAMINER	
Novak, Drue & Quigg LLP 1300 I Street, N.W. Suite 1000, West Tower WASHINGTON, DC 20005			WINSTON, RANDALL O	
ART UNIT	PAPER NUMBER			
	1655			
MAIL DATE	DELIVERY MODE			
10/06/2008	PAPER			

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/682,546

Filing Date: October 10, 2003

Appellant(s): SLIMAK, K. M.

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Thomas P. Pavelko  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed May 28, 2008 appealing from the Final Office action mailed September 27, 2007.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

5,789,012

Slimak

8-1998

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-2, 4-7, 9-14 and 17-20 are rejected under 35 U.S.C. 112, first paragraph because the specification, while being enabled for a method for a dietary intervention of treating particular conditions and symptoms in animals, including humans (i.e. Appellant is enabled for treating the particular conditions and symptoms recited in claim 1 of Application No. 09/889,133 issued as U.S. Patent No. 6,632,461. Also please note Application 10/682,546 being a divisional of parent application 09/889,133) selected from the group consisting of autism, anxiety, arthritis, asthma, colic, congestion, diabetes, digestive upsets, irritable bowel syndrome, eczema, fatigue, migraine headaches, multiple sclerosis, seizures and rashes comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of

tropical root crops selected from the group consisting of white sweet potato, malanga, cassava, true yam, water chestnut, arrowroot, and lotus for a period of at least five days to said patient (as recited in claim 1 of US 6,632,461), the specification does not enable any person in the art in preparing a method for a dietary intervention of treating any and/or all chronic diseases, conditions and symptoms comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Appellant claims a method for a dietary intervention of treating any and/or all chronic diseases, conditions and symptoms comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient. Appellant has reasonably demonstrated on pages 51-88, especially on pages 51-54, examples III-VI of the specification, a method for a dietary intervention of treating particular conditions and symptoms in animals, including humans selected from the group consisting of autism, anxiety, arthritis, asthma, colic, congestion, diabetes, digestive upsets, irritable bowel syndrome, eczema, fatigue, migraine headaches, multiple sclerosis, seizures and rashes comprising a) withholding all food for at

least 5 days, except for tropical root crops b) and feeding a concentrated form of tropical root crops selected from the group consisting of white sweet potato, malanga, cassava, true yam, water chestnut, arrowroot, and lotus for a period of at least five days to said patient.

Appellant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a method for a dietary intervention of treating any and/or all chronic diseases, conditions and symptoms comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient.

Moreover, it should be noted that the state of the prior art at the time the invention was filed did not recognize a method for a dietary intervention of treating any and/or all chronic diseases, conditions and symptoms comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient. For example, Slimak et al. et al. teach (US 5789012 see, e.g. title, column 2, lines 33-35) feeding tropical root crops selected from the group consisting of sweet potatoes, cassava, edible aroids, amaranth, yams lotus and potatoes to treat conditions such as food allergies. Thus, the art is silent regarding the efficacy of appellant's method for a dietary intervention of treating any and/or all chronic diseases, conditions and symptoms comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient. Therefore, appellant's claimed method is highly unpredictable in the art. In addition, the applicant's specification fails to provide guidance or working examples whereby appellant prepares a method for a dietary intervention of treating

any and/or all chronic diseases, conditions and symptoms comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient.

Therefore, it would require undue experimentation for one of skill in the art to practice the invention commensurate in scope with the claims.

#### **(10) Response to Argument**

In regards to the 35 U.S.C. 112, first paragraph rejection, appellant argues Congress has promulgated 35 USC 112, second paragraph to leave it solely to appellants to define their invention. Appellant also argues the courts have previously chastised examiners for attempting to recast the disclosure to the examiner's view of the subject matter of the invention, rather than leaving the subject matter to be defined as the invention to the exclusive realm of the appellant. In the present case, appellant contends that the basis of the examiner's rejection is his mistaken belief that he can view appellant's specification to formulate a belief as to the subject matter that appellant should claim as the invention and then to proceed to reject that subject matter as not being enabled. Further, appellant contends that examiner would like the board to do is to redefine applicant's invention with the examiner's own words i.e., defining a method "of treating particular conditions and symptoms..." which is not at all the claimed method. Appellant concludes that neither claim 1 nor claim 20 specifically refers to treating any symptom or condition and the appellant respectfully submits that the examiner has impermissibly exceeded his authority to recast appellant's invention as a method for treating certain diseases, symptoms or conditions, when the appellant does not claim such a method.

The examiner disagrees with appellant's arguments because the ordinary artisan would ask how one would use "dietary intervention" within appellant's claims. The examiner has concluded that claims must be given their broadest reasonable interpretation (see, e.g. MPEP 2111). The Federal Circuit's *en banc* decision in *Phillips v AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the broadest reasonable interpretation" standard: the Patent and Trademark Office determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." Thus, the examiner has interpreted the term "dietary intervention" within appellant's claims in light of the specification on pages 51-88, especially on pages 51-54, and examples III-VI of the specification to mean to provide the diet as claimed for the specification-disclosed use of treating a particular condition or symptom from a very long list of conditions and symptoms such as those listed in pages 1-2 of the specification and claimed in claim 19. Both the specification and claim 19 recites about a hundred conditions and symptoms that are extremely diverse and unrelated to each other ranging from Alzheimer's disease to ulcerative colitis to temporary blindness. Although the conditions and symptoms recited in claim 19 are not directly claimed as being treated by the dietary intervention, it is clear in light of the specification that by claiming the dietary intervention of claim 1 wherein the animal exhibits at least one condition or symptom selected from the huge list in claim 19, the use of the dietary intervention as claimed is specifically to be used for treating the animal having the condition or symptom as claimed. In fact, the title of the application itself provides clarity as to what the claimed method of dietary intervention is to be

used for: "Use of tropical root crops in effective intervention strategies for treating difficult and complex cases and chronic diseases.". The specification does not teach any other use for the dietary intervention except for treatment of one of the many disclosed conditions and symptoms. Therefore, enablement of the claimed invention must be analyzed in light of the only disclosed use for the claimed dietary intervention, treating a symptom or condition from a huge list of unrelated conditions and symptoms.

Therefore, the examiner has concluded that the claimed invention, as reasonably demonstrated especially on pages 51-54, examples III-VI of the specification, is only enabled for a method for a dietary intervention to treat particular conditions and symptoms in animals, including humans selected from the group consisting of autism, anxiety, arthritis, asthma, colic, congestion, diabetes, digestive upsets, irritable bowel syndrome, eczema, fatigue, migraine headaches, multiple sclerosis, seizures and rashes comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of tropical root crops selected from the group consisting of white sweet potato, malanga, cassava, true yam, water chestnut, arrowroot, and lotus for a period of at least five days to said patient. As claimed, the methods encompass a large and very unpredictable art which includes a huge number of unrelated conditions and symptoms that the application claims can be treated using the same method. Appellant's specification, however, has failed to provide guidance or working examples, or overcome the unpredictable art for the broad range of different conditions and symptoms, to result in an enabled method for a dietary intervention to treat any and/or all chronic diseases, conditions and symptoms comprising a) withholding all food for at

least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root crops for a period of at least five days to said patient.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Randall O Winston  
September 29, 2008

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